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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,727	02/25/2004	Joseph L. Mark	65937-0045	2729

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,727	MARK, JOSEPH L.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 10/10/2008 and 11/19/2008 have been entered.

Notice of Amendment

2. In response to the amendments filed on 10/10/2008 and 11/19/2008, amended claim(s) 1, 8, and 14 is/are acknowledged. The current rejections of the claim(s) 1-30 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-10, 12, 14-23, 25, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 2002/0082519, hereinafter Miller) in view of Moore (US 2,866,457).

5. For claims 1 and 14 Miller discloses a biopsy system (as best seen in Figure 12) comprising a body member (as best seen in Figure 12) and comprising *inter alia*: a vacuum assisted biopsy device (300) (paragraphs 141-146), a first fluid source (400) (as best seen in Figure 12) in fluid communication with a first input port (as best seen in Figure 12), a second fluid source (paragraph 90; "anesthetic") in fluid communication with a second input port, and a fluid connector (around 402) configured to provide the first fluid source in communication with the biopsy device (as best seen in Figure 12) and including a first valve (402) inherently having a cracking pressure and which is selectively opened by a change in pressure within an outlet port (paragraphs 141-146) (as best seen in Figure 12). In regards to claims 9 and 22, Miller discloses that the cracking pressure is less than or equal to a vacuum created in the fluid connector by the biopsy device (paragraph 143). In regards to claims 12 and 25, Miller discloses drawing a predetermined amount of fluid from a fluid source (paragraph 142).

6. For claims 1 and 14, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the first valve is a check valve and the fluid connector includes a second check valve for providing the second fluid source in communication with the biopsy device. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39), comprising inter alia: a first valve (9) comprising a check valve (9) in fluid communication with a first inlet port (around 10) and selectively opened by a change of pressure (column 2 lines 22-44) within an outlet port (around 8), and the fluid connector includes a second check valve (22) for providing the second fluid source (26) in communication fluid

communication with a fluid connector (as best seen in Figure 1). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

7. In regards to claims 2 and 15, Miller in view of Moore does not expressly disclose a duckbill valve member. However, Moore teaches that any check valve well known in the art can be used. Applicant states in the specification that a duckbill-style valve is well known (paragraph 40). The claimed invention would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Miller and Moore teach using valves for fluid management, it would have been obvious to one skilled in the art at the time of the invention to substitute one valve for the other to achieve the predictable results of providing a biopsy system with increased fluid

management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

8. In regards to claims 3, 4, 16, and 17, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the check valves comprise resiliently compressible valve members secured in a valve seat. Moore teaches the check valves comprising resiliently compressible valve members (around and including spring 25 in Figure 1) secured in a valve seat (around 25 in Figure 1). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

9. In regards to claims 5-7 and 18-20, Miller discloses a biopsy system, wherein the first fluid source is an isotonic solution (saline; paragraphs 141-144) and the second fluid source being an anesthetic (paragraph 90; “anesthetic”). Miller discloses the

claimed invention, as set forth and cited above, except for expressly disclosing the second fluid source includes a needleless syringe for holding fluids. Moore teaches the second fluid source includes a needleless syringe (26) for holding fluids. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

10. In regards to claims 8 and 21, the Miller in view of Moore disclose the claimed invention, as set forth and cited above, and in addition Examiner notes that check valves inherently have a predetermined cracking pressure dictated by a change in pressure and Miller in view of Moore teaches the check valve within at least a portion of the biopsy device.

11. In regards to claims 10 and 23, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the cracking pressure is greater than a

vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source. Moore teaches that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Therefore, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

12. In regards to claims 27-30, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the body member comprising a housing comprising a unitary member. Moore teaches the body member comprising a housing comprising a unitary member (11) (as best seen in figure 1) (column 1 lines 63-69). All the claimed elements were known in the prior art and one skilled in the art could have

combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

13. Claims 11, 13, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in view of Moore and further in view of Turturro et al. (US 6,331,165, hereinafter Turturro). Miller in view of Moore discloses the claimed invention, as set forth and cited above, except for expressly disclosing the first and second check valves including female luer fittings and the second fluid source includes a male luer fitting adapted to mate with the female luer fitting of the second check valve. Turturro teaches a biopsy system, comprising *inter alia*: luer fittings (column 18, lines 33-41) for the purpose of providing quick and easy connection and disconnection. Furthermore, the Examiner notes male and female luer fittings are well known in the art and routinely used. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded

predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller in view of Moore and Turturro. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller in view of Moore with the components as taught by Turturro to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

Response to Arguments

14. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection, wherein the new ground(s) of rejection relies upon a new and/or different interpretation of previously applied prior art and/or additional limitations not previously and expressly cited in the rejection using the previously applied prior art.

15. However in view of the rejection using previously applied prior art and in the interest of advancing prosecution, Applicant's arguments filed 10/10/2008 and 11/19/2008 have been fully considered but they are not persuasive. Applicant argues the rejections of the claims under 35 U.S.C. 103(a) as being unpatentable under Miller in view of Moore. The Examiner disagrees, maintains the rejection as set forth, cited, and reiterated above, and in response notes the following:

16. Applicant argues:

a. "Independent claims 1 and 14 positively recite, in part, "the first check valve is selectively opened by a change of pressure within the outlet port." The Examiner relies upon Moore to teach a check valve. However, the check valve of Moore is not taught as being selectively opened when a vacuum is applied to a port thereof. Further, the Examiner incorrectly identifies the "pinch valve 402" of Miller as a check valve. Accordingly, the combination of Miller and Moore cannot teach the recitations of independent claims 1 and 14.

b. "Furthermore, the dependent claims each contain additional features that are also not found in either reference. For example, Moore fails to teach or suggest the resiliently compressible valve member claimed in claims 3 and 16, the predetermined cracking pressure of claims 8 and 21, and the relative level of the cracking pressure of claims 9, 10, 22 and 23. Miller adds no relevant disclosure which would teach or suggest any of the features. For at least this additional reason, the rejection of these claims over Moore and Miller should be withdrawn."

17. In response to Applicant's argument (a), the Examiner respectfully directs Applicants attention to paragraphs 4-6 above.

18. In response to applicant's argument (a) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the check valve… is not taught as being selectively opened when a vacuum is applied to a port thereof") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read

into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

19. In response to Applicant's argument (b), the Examiner notes the spring of Moore comprises a "resiliently compressible valve member" as broadly as structurally claimed.

20. In response to Applicant's argument (b), the Examiner respectfully directs Applicants attention to paragraph 5, 6, 10, and 11 above.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736